

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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**In re: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE LITIGATION**

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) **MDL No. 1456**  
) **Master File No. 01-CV-12257-PBS**  
) **Subcategory Case No. 06-11337**  
) **Hon. Patti B. Saris**

**THIS DOCUMENT RELATES TO:**

)  
) **Magistrate Judge**  
) **Marianne B. Bowler**

*United States of America ex rel. Ven-A-Care of the  
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*  
Civil Action No. 05-11084-PBS

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**DEY PHARMA, L.P., DEY, INC., AND DEY L.P., INC.'S PROPOSED TRIAL PLAN**

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") hereby submit their proposed Dey-only trial plan pursuant to the Court's direction at the March 26, 2010 conference. Dey has shortened its original exhibit list by over half, eliminated several witnesses listed on Dey's original live witness list, and reduced its deposition designations by both the number of deponents and, in some cases, the length of designations. These reductions apply to Dey's defense of both the Medicare and Medicaid claims brought by the DOJ and are reflected in the lists filed as exhibits to this trial plan.

As this Court is aware, the DOJ has filed a Motion to Bifurcate its Medicaid and Medicare claims against Dey. *See* Dkt. 7046. Dey refers the Court to its Opposition to the Motion to Bifurcate, which will be filed on April 27, 2010, for a complete discussion of why the Medicare and Medicaid claims should be tried together. Nonetheless, pursuant to the Court's instructions at the March 26, 2010 conference, Dey hereby sets forth its plan for a Dey-only

Medicare-only trial and a Dey-only Medicare/Medicaid trial, including separate exhibit lists and witness lists for each trial.<sup>1</sup>

## **I. DEY'S MEDICARE-ONLY TRIAL PLAN**

Dey believes that a Medicare-only trial would take between 1 and 2 months. The complexities and scope of this case necessitate the presentation of a variety of witnesses and exhibits. The allegations in the United States' complaint cover Medicare claims over an 11 year period (1992 – 2003 as calculated by plaintiffs' expert). The United States has advised the Court that it seeks single damages of \$340 million, which, if the United States were to prevail – would be trebled. Accordingly, the witnesses and exhibits listed below are reasonable and necessary due to the unprecedented scope of this case.

### **A. Dey's Medicare-Only Witnesses<sup>2</sup>**

The 63 witnesses Dey expects to or may call either live or through deposition designations at a Medicare-only trial are listed in the attached Exhibit A.<sup>3</sup> On Dey's Medicare-only witness list, 21 witnesses are also listed by the DOJ as witnesses that they expect or may

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<sup>1</sup> The DOJ has informed Dey that it does not intend to file new exhibit and witness lists by April 26, even though the DOJ's current lists (1) do not distinguish between the exhibits and witnesses it would offer at a Medicare only and at Medicare/Medicaid trial and (2) include the exhibits and witnesses the DOJ planned to call against Roxane, which has settled subject to formal approvals. Dey has filed a motion requesting that the Court order the DOJ to file new exhibit and witness lists by April 26, which the DOJ has opposed. *See* Dkts. 7070 and 7075. Dey reserves the right to amend its witness lists, deposition designations, and exhibit lists when and if the DOJ advises the Court and Dey of the Dey Medicare-only and Dey Medicare/Medicaid witnesses and exhibits it plans to use at trial.

<sup>2</sup> The parties have agreed that they need not list in their disclosures Keeper of the Records witnesses, if any, whose sole purpose would be to authenticate documents under Fed. R. Evid. 901.

<sup>3</sup> Due to the fact that many of the witnesses are out of the district and the fact that the contours of this case are not yet resolved, Dey is not yet able to determine which of its witnesses will testify in person. Consequently, out of an abundance of caution, Dey has designated deposition testimony for certain witnesses who may testify in person. As the DOJ has, Dey reserves the right to call any witness on this list live, regardless of whether Dey has also designated deposition testimony for the particular witness.

call (if the DOJ does not call these witnesses, Dey has listed these witnesses as will or may call), 13 are witnesses that Dey will call either live or by deposition designations, and 29 are witnesses that Dey may call either live or by deposition designations. The DOJ has listed a total of 114 witnesses, of which 27 are Roxane-related, and 21 which overlap with Dey's witnesses. The common witnesses are likely to include (1) current and former employees of CMS; (2) current and former employees of the OIG; (3) DMERC witnesses; (4) Ven-A-Care witnesses; and (5) some former Dey employees. The remaining Dey witnesses include (1) Dey's experts; (2) current and, to the extent not already called, former Dey employees; (3) compendia witnesses; (4) wholesaler witnesses; (5) pharmacy associations and pharmacists; (6) an employee of Myers & Stauffer; and (7) several State Medicaid witnesses who have knowledge of the industry's understanding of pricing in the pharmaceutical industry, such as AWP, the availability of discounted and undiscounted prices to government entities, and the factors that influence the setting of reimbursement rates to ensure access to care to beneficiaries of governmental assistance programs. The total running time for Dey's Medicare-only deposition designations is approximately 45 hours, which averages to approximately 45 minutes per designated witness. This is on par with the DOJ's current designations, which also average approximately 45 minutes per witness, although in at least one instance, the DOJ's designations are over 4.5 hours.<sup>4</sup>

## **B. Dey's Medicare-Only Exhibits**

Attached as Exhibit B is a list of the exhibits Dey expects to use or may use in a Medicare-only trial.<sup>5</sup> Dey reduced its original exhibit list by eliminating over 5,400 exhibits in

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<sup>4</sup> This total does not include the time for the DOJ's deposition designations of Roxane witnesses, as Roxane has a settlement in principle and those designations are not properly included in the Dey case.

<sup>5</sup> The exhibits listed in Exhibit B and in Dey's Medicare/Medicaid Exhibit List, Exhibit D, are ones Dey marks for identification, for admission in evidence at trial, and/or from which Rule 1006 material

creating its Medicare-only exhibit list. Meanwhile, the DOJ's list of 897 exhibits is comprised of approximately 50% Roxane documents, and hundreds of pages for things such as Medicare arrays grouped together as single exhibits. Dey's Medicare-only list consists of 1,972 exhibits, of which 270 are arrays. In addition to the arrays, the DOJ and Dey's exhibit lists contain overlapping exhibits including price notification letters, program memoranda, launch materials, and other documents. Dey's exhibits largely fall into the following categories: Dey documents, such as price notification letters, product launch and training materials, contract files, and monthly sales reports; pricing arrays from the DMERCs; Medicare documents including program memoranda, correspondence with the DMERCs, and other DMERC documents; Government Reports from the OIG, GAO, CBO, and CMS; Myers & Stauffer Reports; other CMS documents relating to issues of the case; statutes and regulations; data; documents relied on by Dey's experts; and summary exhibits.

## **II. DEY'S MEDICARE/MEDICAID TRIAL PLAN**

Dey believes that a Medicare/Medicaid trial would take between 3 and 4 months. The allegations in the United States' complaint cover Medicare claims submitted over a 12 year period, and Medicaid claims submitted to 47 states and the District of Columbia from over 18 years (1992 to date). Given the scope of these claims, as compared to other AWP trials that have

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may be presented. Dey reserves the right to introduce any exhibits or portions thereof identified by Plaintiff the United States of America and Relator Ven-A-Care of the Florida Keys, Inc. (collectively, "Plaintiffs"). Dey reserves the right to use materials considered by Plaintiffs' experts, working files, data and programs from Plaintiffs' experts, and other back-up material from Plaintiffs' experts in connection with Dey's cross-examination of those experts. References to depositions, deposition exhibits, summary judgment exhibits, experts, or other pleadings in the exhibit list are solely for purposes of identification, and Dey reserves the right to introduce each listed exhibit in any context. Dey also reserves the right to withdraw exhibits presently included on its list based on the Court's rulings on any pending motion, including motions in limine, which will be filed in accordance with the schedule set by the Court. Further, Dey reserves the right to supplement its exhibit list in order to rebut any additional evidence or argument offered by the Plaintiffs at trial.

taken place, and the fact that, as this Court has observed, each state Medicaid program is unique, Dey's witness lists, deposition designations, and exhibit lists are reasonable and necessary. The addition of the Medicaid claims would result in the following additions to Dey's Trial Plan.

**A. Dey's Medicare/Medicaid Witnesses**

The 139 witnesses Dey expects to or may call at a Medicare/Medicaid trial either live or through deposition designations are listed in the attached Exhibit C. On Dey's Medicare/Medicaid witness list, 34 witnesses are listed by the DOJ as witnesses that they expect or may call (if the DOJ does not call these witnesses, Dey has listed these witnesses as will or may call), 37 are witnesses that Dey will call either live or by deposition designations, and 68 are witnesses that Dey may call either live or by deposition designations. 63 of the witnesses on Dey's Medicare/Medicaid list are the same as those in Dey's Medicare-only witness list, and the additional 76 witnesses include additional State Medicaid witnesses, CMS witnesses focusing on Medicaid, as well as limited additional testimony from certain CMS, OIG, and other witnesses relating to Medicaid. For most states, Dey has only designated 1 or 2 witnesses and less than 2 hours of testimony.<sup>6</sup> This is extraordinarily economical as compared to the presentation of testimony in other AWP cases. For example, in the AWP case in Kentucky against Sandoz, 6 Medicaid officials were presented either live or by deposition over the course of 4 days. In addition, the Commonwealth of Massachusetts identified 35 witnesses to appear either live or by video in a single state AWP case. Multiplied by the 47 states and Washington D.C. at issue here, that would bring Dey to 1,680 witnesses.

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<sup>6</sup> There are some instances, such as in litigating states, where there is more than two hours per state.

**B. Dey's Medicare/Medicaid Exhibit List**

Attached as Exhibit D is a list of the exhibits Dey expects to use or may use in a Medicare/Medicaid trial. Dey's Medicare/Medicaid list consists of 3,845 exhibits, which includes the exhibits from the Medicare-only list and an additional 1,873 exhibits. The additional exhibits can be divided into the following categories: Medicaid-specific CMS documents, and state-specific documents, such as state plan amendments, state correspondence, and documents evidencing state-specific Medicaid policies and government knowledge. This is an average of 39 documents per state. Dey reduced its original exhibit list by eliminating over 3,500 exhibits in creating its Medicare/Medicaid exhibit list. Of the exhibits listed in Dey's Medicare/Medicaid exhibit list, 222 overlap with those previously identified by the DOJ, further reducing the total amount of exhibits that would be presented at a Medicare/Medicaid trial.

For most of the 47 states and Washington D.C., Dey designated fewer than 50 exhibits that are specific to that state's Medicaid program. For many of the 47 states and Washington D.C., the total is below 20 exhibits. Dey has not designated more than a few hundred exhibits for any single state. Compared to exhibit designations in other pharmaceutical pricing cases brought by the states, Dey's designations are, on a state-by-state basis, quite limited. For instance, in the trial of the case brought by Massachusetts against Warrick – a case involving a single state Medicaid program – Warrick designated 1564 exhibits, and the Commonwealth of Massachusetts designated 550. Exhibit lists in other state Medicaid trials have been equally voluminous:

| Case                    | Plaintiff Exhibits | Defendant Exhibits            |
|-------------------------|--------------------|-------------------------------|
| Alabama v. Watson       | 1058               | 2620                          |
| Wisconsin v. Pharmacia  | 1261               | 939                           |
| Alabama v. Sandoz       | 1272               | 1792                          |
| Alabama v. Astra Zeneca | 1529               | 1557                          |
| Alabama v. Novartis/GSK | 1565               | Novartis – 1720<br>GSK – 1911 |
| Kentucky v. Sandoz      | 2577               | 2753                          |
| Kentucky v. GSK         | 464                | 495                           |

If the number of exhibits designated by the Commonwealth of Massachusetts for a single state AWP case were multiplied for the 48 Medicaid programs at issue here, the total exhibits would be 26,400. Thus, the Dey Medicare/Medicaid list of 3,774 exhibits is narrowed and reasonable.

At the end of the day, the DOJ chose to bring a nationwide case against Dey both as to Medicaid and Medicare over three drugs. Dey has complied with the Court's urging that trial plans be proposed which are manageable. This has been done in a vacuum given the DOJ's unwillingness to identify which witnesses and which exhibits it would call at a Dey-only Medicare or a Dey-only Medicare/Medicaid trial, despite the Court's direction at the March hearing. Dey reserves its right to amend these plans once it knows what the DOJ actually intends to use at trial.

Dated: April 26, 2010

Respectfully Submitted,

KELLEY DRYE & WARREN LLP

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on April 26, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Sarah L. Reid  
Sarah L. Reid